As of July 2022

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
cyclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	U.S.					May-2022	
				China					Apr-2022	

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Launched successively in European countries since October 2018. Launched successively in Asian countries after receiving approval for an indication extension for Ikervis in August 2019. Launched in November 2019 in Canada. Launched in May 2022 in the U.S. and received marketing approval in April 2022 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 / DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan					Jun-2022	

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Received manufacturing and marketing approval in June 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010904	Fuchs endothelial corneal dystrophy	Joint development with ActualEyes	Japan France India	(Phase 2a)					

An ophthalmic suspension which treats Fuchs endothelial corneal dystrophy via mTOR inhibition. Started Phase 2a in US, France and India in May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial.)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010905	Meibomian gland dysfunction	Original	Japan	(Phase 2a)					

An ophthalmic suspension which improves meibomian gland function via mTOR inhibition. Started Phase 2a in October 2021 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost/ timolol maleate	STN1011101 /DE-111A	Glaucoma/ Ocular hypertension	Co-development with AGC	China						

A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						

An H_1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. Ophthalmic cream. Started Phase 3 in February 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepag isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.				May-2022		
				Japan						Nov-2018
				Asia						Feb-2021

An EP2 receptor agonist with a new mechanism of action. Re-submitted for marketing approval in May 2022 in the U.S. Launched in November 2018 in Japan. Launched successively in Asian countries since launch in February 2021 in Korea.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	STN1012600 / DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.						
				Japan		(Phase 2b)				
				Europe		(Exploratory study)				

A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Completed an additional Phase 2 in December 2021 in the U.S. Completed Phase 2b in Japan. Started Phase 2 (exploratory study) in September 2021 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012700 / DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan			(Phase 2/3)			
				China			(Phase 2/3)			
				Asia						

Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Conducting Phase 2/3 from August 2019 in Japan. Started Phase 2/3 in June 2022 in China. Completed P2 in April 2020 in Asia.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012701 / SYD-101	Myopia	Sydnexis Inc.	Europe						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Sydnexis Inc., the licensor, is conducting Phase 3 trial in Europe and the U.S. Santen has obtained the exclusive license for Europe, Middle East and Africa.										

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100 / DE-128	Glaucoma	Original	Japan					Jul-2022	
				Europe					Apr-2019	
				Asia					Sep-2021	
A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Launched (soft launch) in July 2022 in Japan. Launched in Europe in April 2019. Filed successively for marketing approval in Asian countries since March 2020 and received approval in Singapore and other countries since September 2021.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 /DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						
An ophthalmic emulsion of a prostaglandin F2α derivative, for the treatment of glaucoma and ocular hypertension. Completed Phase 3 in March 2022 in Europe and Asia										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						
Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduce mydriasis by selectively inhibiting a subtype of receptors. Completed Phase1 in September 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
Ursodeoxycholic acid	STN1013600	Presbyopia	Original	Japan						
Improvement of presbyopia by improving lens elasticity. Completed Phase 1 in April 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesylate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Aerie	Japan						
				Europe						
				Asia				Mar-2022		
A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Aerie in the U.S. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe. Filed for marketing approval in March 2022 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesylate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Aerie	Europe						
				Asia				May-2022		
A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin F_2α derivative. Developed and sold by Aerie in the U.S. Received marketing approval in Europe. Filed for marketing approval in May 2022 in Asia.										

Changes from Q4 FY2021 (May 10, 2022)

Dev. Code	Changes
STN1008903 / DE-089C	Received manufacturing and marketing approval in June 2022 in Japan.
STN1010904	Started Phase 2a in U.S., France and India in May 2022.
STN1011700 / DE-117	Re-submitted for marketing approval in May 2022 in the U.S.
STN1012700 / DE-127	Started Phase 2/3 in June 2022 in China.
STN2000100 / DE-128	Launched (soft launch) in July 2022 in Japan.
STN1014000 / PG-324	Filed for marketing approval in May 2022 in Asia.